REMARKS

The election of claims 1-7, 11, 23-27, 34-37 without traverse is noted.

The specification has been checked and various spelling and typographical and grammatical errors have been corrected. Also, the Abstract of the Disclosure has been revised in accordance with MPEP §608.01(b) and is newly presented herewith on an attached separate sheet.

The objection to informal drawings is noted. It is requested that the requirement for formal drawings be held in abeyance pending allowance of this application.

Dependent claim 5 has been rejected under 35 USC §112, ¶1, as containing subject matter not described in the specification. This rejection is respectfully traversed.

Claim 5 as originally filed in this application constitutes a portion of the specification, and the subject matter of claim 5 is submitted to be directly connected to the subject matter of claim 1 from which it depends regarding a subxiphoid incision and "... one additional subxiphoid incision." It is therefore respectfully submitted that the subject matter of dependent claim 5 is adequately supported by the specification as filed, and that dependent claim 5 is patentable to applicant.

Claims 1-4, 6-7 and 25-27 have been rejected under 35 USC §102(b) as being anticipated by Oliva '156. This rejection is respectfully traversed.

These claims, which have been amended merely to define the invention more specifically, now specifically recite variously "inserting a rigid endoscopic cannula having a transparent tip at a distal end thereof; (c) advancing the tip of said endoscopic cannula through tissue to the pericardium under endoscopic visualization through the tip", and "laterally expanding a passage through tissue from the subxiphoid incision to provide a dilated cavity to facilitate insertion of the endoscopic cannula", and "said opening in the pericardium is provided by manipulating an entry instrument through the at least one access port of the rigid endoscopic cannula", and "gripping a flap of the pericardium under endoscopic visualization using an entry instrument introduced through the at least one access port of the endoscopic cannula".

These aspects of the claimed invention facilitate blunt dissection of tissue under visualization through an endoscope and the tip along a path from the subxiphoid incision toward the pericardium. The rigid endoscopic cannula promotes controlled and visualized passage through the diaphragm without fear of inadvertent puncture through the pericardium into the heart. The transparent tip at the distal end of the rigid endoscopic cannula greatly facilitates separating the muscle fibers of the diaphragm with diminished

resistance relative to traditional insertion of a large trocar that is necessary to accommodate a pericardioscope or other surgical instruments.

These aspects of the claimed invention are not disclosed in Oliva '156 which relies upon a flexible body analogous to a gastroendoscope (Col. 2, lines 47-50). This flexible instrument is not understood to include a transparent tip at a distal end that is capable of penetrating and dissecting tissue along a path from a subxiphoid entry incision to the pericardium in the manner as claimed by applicant. As Oliva '156 is currently understood, this reference discloses a difficult procedure that is prone to inadvertently injuring the heart. Specifically, Oliva '156 performs a subxiphoid incision and inserts a trocar through the muscle tissue of the diaphragm and the loose connective tissue along a path to the parietal pericardium. Trocars are commonly inserted without endoscopic visualization, and the diaphragm presents significant resistance to insertion of a trocar of sufficient size to accommodate a pericardioscope. There is therefore potential for puncturing the pericardium and injuring the heart in the absence of visual guidance as the trocar is inserted in accordance with the procedures disclosed in Oliva '156.

Nor is there any disclosure in this reference of any procedure for gripping and cutting a flap of the pericardium while spaced away from the

underlying heart, in a manner as claimed by applicant. At best, this reference is understood to rely upon scissors for incising the pericardial sac (Col. 2, lines 50-52), with the concomitant danger of puncturing the underlying heart. It is therefore respectfully submitted that Oliva '156 provides no disclosure or hint of suggestion of applicant's claimed method, and that claims 1-4, 6-7, and 25-27 as amended are now patentable to applicant.

Claims 34-37 have been rejected under 35 USC §102(e) as being anticipated by Roth '074. This rejection is respectfully traversed.

These claims, which have been amended merely to define the invention with greater particularity, specifically recite "laterally expanding the sheath responsive to passing the endoscopic cannula through the expandable sheath to form a working cavity in dilated tissue", and "laterally expanding the sheath responsive to withdrawing the endoscopic cannula from the sheath in a direction toward the proximal end thereof", and "dilating the working cavity to larger lateral dimensions than the endoscopic cannula responsive to insertion into the expandable sheath of surgical tools having dimensions greater than the cannula", and "advancing the surgical tool within the expandable sheath toward a distal end thereof to laterally expand the expandable sheath".

These aspects of the claimed invention facilitate sufficient dilation of tissue along the dissected cavity to accommodate a surgical instrument that is introduced therethrough toward the heart.

These aspects of the claimed invention are not disclosed in the cited reference. At best, the segment (col. 4, lines 12-20) of the specification cited by the Examiner merely describes a channel traversing the length of the shaft, and offers no hint or suggestion of expanding a laterally-expandable sheath in the manner as claimed by applicant. It is therefore respectfully submitted that claims 34-37 define the invention with sufficient particularity and distinctiveness to be patentable over the cited art.

Claims 11, 23, 24 have been rejected under 35 USC §103(a) as being unpatentable over Oliva '156 in view of Vaska et al. '605. This rejection is respectfully traversed.

These dependent claims are further limited from the predecessor claims by the specific recitations of "said surgical instrument advanced in step (d) is a device for performing epicardial mapping", and "said opening is formed at a location near the apex of the heart", and "the rigid endoscopic cannula is advanced during step (f) to a location at the anterior region of the heart and is then swept throughout regions including the posterior region of the heart".

These aspects of the claimed method invention promote controlled penetration of tissue with the aid of a rigid endoscopic cannula, along the path from the subxiphoid incision to the pericardium, and then through the pericardium to selected regions of the heart, all under visualization through the endoscopic cannula.

These aspects of the claimed invention are not shown or suggested by the cited references considered either alone or in the combination proposed by the Examiner.

Specifically, Oliva '156 discloses use of a flexible body device that can be bent or otherwise shaped under control from the proximal end of the body, and such flexible body is not conducive to, or appropriate for, tissue dissection through diaphragm muscle for reasons as discussed in the above Remarks. And, Vaska et al. '605 B1 similarly relies upon flexible-body instruments inserted through a thoracic incision and through a pericardial penetration (Col. 3, lines 8-57). Thus, merely combining these references in the manner proposed by the Examiner is deficient of disclosure of the defined procedures, and fails to establish even a *prima facie* basis from which a proper determination of obviousness can be made. It is therefore respectfully submitted that the dependent claims 11, 23-24 as limited by the specific recitations of the predecessor claims and as further restricted by the

recited limitations discussed above are now patentably distinguishable over the cited art.

Reconsideration and allowance of all elected claims are solicited.

Respectfully submitted,
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ATTACHMENT: APPLICATION REVISIONS

APPLICATION REVISIONS

In the Specification

Replace first paragraph on page 4, as follows:

--Various other schemes and devices have been previously devised in an attempt to enter the pericardium via a small portal of entry, or via a percutaneous puncture site. None of these systems permit reliable, safe entry under direct, endoscopic visualization. U.S. Patent No. 5,931,810 (Grabek) describes a grasping instrument with jaws that grasp the pericardium followed by advancement of a needle through a bore in the shaft of the instrument. [depicts a grasping instrument with jaws.] The needle extends between the closed jaws of the device, into the pericardium. This concept suffers from unreliability, as it is difficult to ensure that the needle will pierce between two layers of pericardium that are compressed by the jaws of the device, without an active technique of holding the two opposed layers of pericardium apart. Thus, as there is no central cavity in a flap of pericardium grasped by the instrument jaws, a needle advanced down a central bore of the instrument may easily end up outside of the pericardium, or embedded in the pericardium, instead of lying between the two layers of

pericardium pinched together by the jaws. Also, axial advancement of the needle carries the potential of myocardial puncture. Needle entry with the Grabek device must be verified by subsequent passage of a guidewire into the pericardial sac, or by infusion of fluid or contrast material through the needle into the pericardial cavity.--

Replace last paragraph on page 4 to the top of page 5, as follows:

--U.S. Patent 5,071,428 (Chin et al.) describes a clamp with distal[.] points that grasp a flap of pericardium, allowing a guidewire to be advanced within tubular guides to puncture through the pericardium. A tube may follow the guidewire into the intra pericardial space. This design may cause myocardial trauma due to the sharp pointed grasping clamp. The multiple steps of pericardial grasping, pericardial puncture, guidewire advancement, and catheter insertion render this technique impractical.--

Replace first paragraph on page 6, as follows:

--In an alternative embodiment, the cannula of the endoscopic cannula is articulable, and the cannula further comprises a wire lumen, a wire, and an articulating lever. The wire is positioned within the wire lumen, having a distal end attached to a distal end of the cannula. The articulating lever is

positioned near the proximal end of the cannula, attached to the proximal end of the wire, for tensioning the wire in a first position to cause the distal end of the cannula to bend away from alignment with the proximal end of the cannula, and for relaxing the wire in a second position to position the distal end of the cannula substantially [parallel to] aligned with the proximal end of the cannula.--

Replace last paragraph on page 7 to the top of page 8, as follows:

--In a preferred method, the pericardial entry device is advanced tangentially to the pericardium to allow the [gasping] grasping tool to grasp a flap of the pericardium without endangering the underlying heart. Once a flap of the pericardium is [gasped] grasped, the cutting tool is extended to the cut the flap, creating a small opening into which other surgical tools may be introduced. In a preferred embodiment, the cutting tool is a tubular cutting device which creates a circular opening which facilitates the introduction of other surgical tools. Due to the small circumference of the tubular cutter, the opening in the pericardium is also small. One embodiment of a method of performing a cardiac procedure used in conjunction with the described apparatus comprises first making a single subxiphoid incision to provide initial access into the patient's body, inserting

an endoscopic cannula into the incision, advancing the endoscopic cannula to the mediastinum under endoscopic visualization, and performing the surgical procedure with the mediastinum. Optionally, the method further includes initially providing a dilated cavity for passing the endoscopic cannula into the mediastinum as previously described, and performing the surgical procedure within the mediastinum.--

Replace paragraph 10, on page 11, as follows:

--Figure 7B is a perspective view of an endoscopic cannula with an access port with an [articulable] articulatable head in accordance with the present invention.--

In the Abstract

Substitute the corrected Abstract of the Disclosure as set forth on the attached separate sheet.

In the Claims

1. (Amended) A method of performing a cardiac procedure, comprising the steps [of] for:

(a) making a subxiphoid incision to provide an entry point for an endoscopic cannula[, wherein said endoscopic cannula has] having at least one access port;

(b) inserting [said] a rigid endoscopic cannula [into the incision] having a transparent tip at a distal end thereof;

(c) advancing the tip of said endoscopic cannula through tissue to the pericardium under endoscopic visualization through the tip; and

(d) advancing a surgical instrument through said at least one access port of said endoscopic cannula.

2. (Amended) A method according to claim 1, further comprising the steps [of] for:

(e) after step (c) and before step (d), providing an opening in the pericardium for the advancement of said endoscopic cannula into the pericardium;

(f) after step (e) and before step (d), advancing said endoscopic cannula into the pericardium through said opening; and

(g) after step (d), performing the surgical procedure on the heart.

3. The method of claim 1, wherein the subxiphoid incision has a length no longer than required for insertion of the endoscopic cannula.

4. The method of claim 1, wherein only a single subxiphoid incision is made.

5. The method of claim 1, wherein at least one additional subxiphoid incision is made during step (a), and the method also includes the step of:

(e) inserting an additional surgical instrument through said at least one additional incision.

6. (Amended) The method of claim 1, further comprising:

[(e) before step (b), using a dilation tool] laterally expanding a passage through tissue from the subxiphoid incision to provide a dilated cavity to facilitate insertion of the endoscopic cannula.

7. (Amended) The method of claim 2, wherein said opening in the pericardium is provided by manipulating [a pericardial] an entry instrument through the at least one access port of the rigid endoscopic cannula.

8. (Unexamined) The method of claim 7, wherein the endoscopic cannula has a lumen and the pericardial entry instrument is advanced to the pericardium through the lumen.

9. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is a stapler for stapling off the atrial appendage.

10. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is an ablation device.

11. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is a device for performing epicardial mapping.

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12. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is a device for performing intrapericardial drug delivery.

13. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is a device for performing a myocardial biopsy.

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15. (Unexamined) The method of claim 1, wherein said surgical

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instrument advanced in step (d) is a needle for injecting cardiac muscle cells or undifferentiated satellite cells for cellular cardiomyoplasty.

16. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is a cannula for injecting pharmacological agents for angiogenesis.

17. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is a robotic, cutting, stabilizing, or

anastomotic instrument for performing coronary artery bypass or coronary artery bypass grafting.

18. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is an energy probe or mechanical piercing element for piercing the heart muscle for transmyocardial revascularization.

19. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is a device for creating a pericardial window.

20. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is a stapler for stapling off the atrial appendage.

21. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is a suture loop for cinching off the atrial appendage.

22. (Unexamined) The method of claim 1, wherein said surgical instrument advanced in step (d) is a clip for sealing off the atrial appendage.

23. (Amended) The method of claim 2, wherein said [endoscopic cannula is advanced during step (f) to] <u>opening is formed at</u> a location near the apex of the heart.

24. (Amended) The method of claim 2, wherein the rigid endoscopic cannula is advanced during step (f) to a location at the anterior region of the heart and is then swept [to] throughout regions including the posterior region of the heart.

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25. (Amended) The method of claim 2, wherein step (e) includes the steps [of] for:

gripping a flap of the pericardium under endoscopic visualization using [a pericardial] an entry instrument introduced through the at least one access port of the endoscopic cannula; and

cutting said flap of the pericardium while spaced away from the underlying heart to create an opening in the pericardium under endoscopic visualization.

26. (Amended) The method of claim 25, wherein step (e) further comprises the step [of] for:

aligning the [pericardial] entry instrument substantially tangentially to the pericardium under endoscopic visualization while gripping the flap of the pericardium.

27. (Amended) The method of claim 25, wherein the cutting step further comprises cutting the flap of the pericardium while spaced away from the underlying heart.

28. (Unexamined) A method of performing a surgical procedure on a mediastinal organ other than the heart, comprising the steps of:

(a) making a subxiphoid incision to provide an entry point for an endoscopic cannula, wherein said endoscopic cannula has at least one access port;

(b) inserting said endoscopic cannula into the incision;

(c) advancing said endoscopic cannula to a surgical site within the mediastinum under endoscopic visualization; and

(d) advancing a surgical instrument through said at least one access port of said endoscopic cannula.

29. (Unexamined) The method of claim 28, further comprising the step of:

(e) after step (d), performing the surgical procedure on said mediastinal organ.

30. (Unexamined) The method of claim 28, wherein the subxiphoid incision has a length no longer than required for insertion of the endoscopic cannula.

31. (Unexamined) The method of claim 28, wherein only a single subxiphoid incision is made.

32. (Unexamined) The method of claim 28, wherein at least one additional subxiphoid incision is made during step (a), and the method also includes the step of:

(e) inserting an additional surgical instrument through said at least one additional incision.

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33. (Unexamined) The method of claim 28, further comprising:

(e) before step (b), using a dilation tool to provide a dilated cavity to facilitate insertion of the endoscopic cannula.

34. (Amended) A method of performing a cardiac procedure with [an] a rigid endoscopic cannula having [an] a laterally expandable sheath overlying the endoscopic cannula, comprising[:] the steps for:

(a) incising skin overlying an entry point for the cardiac procedures;

(b) inserting [an] the rigid endoscopic cannula with [an] the expandable sheath into the incision;

(c) advancing the endoscopic cannula [to] through tissue toward the pericardium under endoscopic visualization; and

(d) [dilating a working cavity] laterally expanding the sheath responsive to passing the endoscopic cannula through the expandable sheath[.] to form a working cavity in dilated tissue.

35. (Amended) The method of claim 34 wherein dilating the working cavity further comprises:

[dilating a working cavity] laterally expanding the sheath responsive to [removing] withdrawing the endoscopic cannula [to a point near] from the sheath in a direction toward the proximal end [of the expandable sheath] thereof.

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36. (Amended) The method of claim 34 further comprising the step [of] for:

(e) dilating the working cavity to larger lateral dimensions than the endoscopic cannula responsive to insertion into the expandable sheath of surgical tools having dimensions greater than the endoscopic cannula [into the expandable sheath].

37. (Amended) The method of claim 34 further comprising the steps [of] for:

(e) inserting into a proximate end of the expandable sheath a surgical tool for performing a cardiac procedure [into a proximate end of the expandable sheath] in which the surgical tool has a maximal lateral dimension greater than a maximal lateral dimension of the expandable sheath overlying the endoscopic cannula;

(f) advancing the surgical tool within the expandable sheath [to] toward a distal end [of] thereof to laterally expand the expandable sheath; and

(g) performing a cardiac procedure using the surgical tool.

38. (Unexamined) An endoscopic cannula, comprising:

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a cannula, having an elongated body having arcuate shape and defining at least one lumen;

a tip positioned at a distal end of said elongated body, said tip having a tapered distal end and being transparent for facilitating visualization through said tip; and

an endoscope, positioned at least partially in said at least one lumen for providing visualization of a surgical procedure through said transparent tapered tip.

39. (Unexamined) The endoscopic cannula of claim 38, wherein said cannula is composed of a flexible material.